

09/914659  
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 approved for use through 10/31/2002, OMB 0651-0031

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PTO/SB/08B (06/00)

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				Application Number		
				Filing Date		August 31, 2001
				First Named Inventor		James, et al.
				Group Art Unit		1651
				Examiner Name		LILLIAN
				Attorney Docket Number		18872.0107
Sheet	2	of	2			

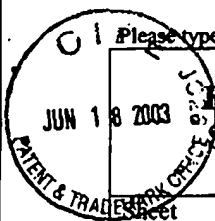
OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate, title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T2
g	1	DUBOS et al., "Media for Tubercle Bacilli", in AM.REV.TUBERC., Vol. 56, 1947, pp. 334-345.	
	2	WAYNE L.G. (1994) "Cultivation of Mycobacterium tuberculosis for Research Purposes" in Tuberculosis: Pathogenesis, Protection, and Control, published by the American Society for Microbiology, pp. 73-83, BR Bloom (ed.) ASM Press.	
	3	LOWRIE, D.B., ABER, V.R., and JACKETT, P.S. (1979). Phagosome-lysosome fusion and cyclic adenosine 3:5-monophosphate in macrophages infected with <i>Mycobacterium microti</i> , <i>Mycobacterium bovis</i> BCG and <i>Mycobacterium Leraemurium</i> . J.Gen. Micro. 110:431-441.	
	4	RATLEDGE, C. (1983). Nutrition, growth and metabolism. pp. 185-271. In: Ratledge, C., and J. Stanford (eds.), The biology of mycobacteria: immunological and environmental aspects. Acad Press.	
	5	WAYNE, L.G. (1977). Synchronized replication of <i>Mycobacterium tuberculosis</i> . Infect. Immun. 17:528-530.	
	6	FROMAN, S., WILL, D.W. and BOGEN, E. (1954). Bacteriophage active against virulent mycobacterium tuberculosis. (I) Isolation and Activity. American J. of Public Health, vol. 44, pp.1326-1333.	
	7	CM MCCARTHY et al.: "Maximum growth rate of <i>Mycobacterium avium</i> in continuous culture or chronically infected BALB/c mice", MICROBIOS, vol. 52, 1987, pp. 97-103, CAMBRIDGE GB.	
	8	LG WAYNE: "Dynamics of submerged growth of <i>Mycobacterium tuberculosis</i> under aerobic and microaerophilic conditions", AMERICAN REVIEW OF RESPIRATORY DISEASE, vol 114, no. 4, October 1976 (1976-10), pp. 807-811.	
	9	"DIFCO Manual: Dehydrated Culture Media and Reagents for Microbiology" 1984, DIFCO Laboratories, Detroit, USA.	
g	10	MCCARTHY, Continuous Culture of <i>Mycobacterium Avium</i> Limited Ammonia, 1982, pp. 193-197.	

Examiner Signature		Date Considered	11/12/03
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 Applicant is to place a check mark here if English Translation is attached.

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PTO/SB/08B(02/03)

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Application Number	09/914,659
Filing Date	August 31, 2001
First Named Inventor	James A. al.
Group Art Unit	1651
Examiner Name	LILLING
Attorney Docket Number	18872.0107

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate, title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
JLF	1	VAN HEMERT, <i>Vaccine Production as a Unit Process</i> , BCG Vaccine (1971) pp. 110-116	
	2	NYABENDA ET AL., <i>The Production of Mycobacterial Antigens by Homogeneous Culture in a Fermentor</i> , Journal of Biological Standardization (1988) Vol. 16, pp. 259-267	
	3	BLOCH, M.D. ET AL., <i>Variations in Virulence Effected by Tween 80 and Thiosemicarbazone</i> , J. Exp. Med. (1953) Vol. 97, pp. 1-16	
	4	GHEORGHU ET AL., <i>The Stability and Immunogenicity of a Dispersed-Grown Freeze-Dried Pasteur BCG Vaccine</i> , Journal of Biological Standardization (1988) Vol. 16, pp. 15-26	
	5	GHEORGHU ET AL., <i>The Effects of Dispersed or Surface Grown Cultures, Manufacture and Control Methods on BCG Standardization</i> , Develop. Biol. Standard. (1986) Vol. 58, pp. 191-205	
	6	UNGAR, M.D. ET AL., <i>Preparation and Properties of a Freeze-Dried B.C.G. Vaccine of Increased Stability</i> , British Medical Journal (October 27, 1962) pp. 1086-1089	
	7	KIM, <i>High-Viability Lyophilized Bacille Calmette-Guerin Vaccine Produced by Deep-Culture Technique</i> , Appl. and Environ. Microbiol. (1977) Vol. 34, No. 5, pp. 495-499	
	8	DUBOS ET AL., <i>Production of BCG Vaccine in a Liquid Medium Containing Tween 80 and a Soluble Fraction of Heated Human Serum. I. Production and Viability of the Culture.</i> , J. Exp. Med. (1950) Vol. 91, pp. 163-168	
	9	SIRKS ET AL., <i>Production of Freeze-Dried BCG-Vaccine</i> , Symp. Series Immunobiol. Standard. (1971) Vol. 17, pp. 163-168	
	10	FENNER ET AL., <i>Production of BCG Vaccine in a Liquid Medium Containing Tween 80 and a Soluble Fraction of Heated Human Serum. II. Antigenicity of the Culture After Various Periods of Storage.</i> , J. Exp. Med. (1949) Vol. 91, pp. 269-284	
JLF	11	DUBOS ET AL., <i>Media for Tubercle Bacilli</i> , Am. Ref. Tuberc. Pulm. Dis. (1947) Vol. 56, pp. 334-345	

Examiner Signature	<i>Robert J. Selling</i>	Date Considered	11/12/03
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<sup>1</sup> Applicant's unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English Translation is attached.

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Application Number	09/914,659
Filing Date	August 31, 2001
First Named Inventor	James et al.
Group Art Unit	6651
Examiner Name	LIMING
Attorney Docket Number	18872.0109

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Examiner Signature	<i>Heriberto Lopez</i>	Date Considered	11-7-03
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